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10/786,016	02/26/2004	Tomoaki Hoshino	021310A	3540

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,016	HOSHINO, TOMOAKI	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24 and 32-50* is/are pending in the application.

4a) Of the above claim(s) *41-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 32-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *24 and 32-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election with traverse of Group II invention, claims 24, 32-39 and 40, directed to an antibody to IL-18R, filed on 22 March 2007 is acknowledged. The traversal is on the ground(s) that claims 24 and 34 are analogous to Markush claims, and the "species" recited in the claims share both a common utility and substantial structural feature essential to the utility, that regarding Markush type claims, according to MPEP, it is improper to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, and unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility, and that no prima facie showing of a serious burden on the examiner has been made as classification for certain groups is the same, groups I and II, for example. This is not found persuasive for the following reasons: first, the claims are not considered analogous to Markush claims because they are not in proper Markush format. Further, even if they were considered as Markush claims, there is absolutely no shared structural feature among the products claimed (or in the groups). Finally, with respect to the classification argument, according to MPEP (§808.02 [R-5]), a serious burden may be established by any *one* of the following: (A) separate classification thereof; (B) a separate status in the art when they are classifiable together; or (C) a different field of search. In the instant case, although certain groups are under the same classification, they are independent or distinct inventions because they are physically and functionally distinct chemical entities, and share neither structure nor function. For example, the antibody for IL-18 (group I) and the antibody to IL-18R (group II) share neither structure nor function, and a search of antibody for IL-18 would not necessarily reveal prior art for antibody to IL-18R. Therefore, each group has a separate status in the art, and requires a different field of search of the prior art, and search all groups constitute serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Currently, claims 24 and 32-50 are pending, and claims 24 and 32-40 are under consideration to the extent that they read on the elected invention. Claims 41-50 are withdrawn from further consideration as being drawn to a non-elected invention.

Withdrawal of Objections and Rejections:

The prior art rejection of claim 24 under 35 U.S.C. 102(b) as being anticipated by Taniguchi et al. (J. Immuno. Meth., 1997, 206:107-113) is withdrawn in view of applicant's election, and new ground of rejection.

Formal Matters:

Claims

Claim 40 is objected to for encompassing a non-elected subject matter, a monoclonal antibody for IL-18. The applicant is required to amend the claims to read only upon the elected invention.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 32-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have not pointed out, nor can the Examiner locate, the basis in the specification for the limitation "the composition is in a form suitable for administration to humans" in the newly amended claim 24 and the new claim 35.

This is a new matter rejection.

Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 24 remains rejected, and the new claims 32 and 33 are rejected under 35 U.S.C. 101 because the claimed invention reads on non-statutory subject matter, for the reasons of record set forth in the last Office Action mailed on 29 June 2006, at pages 2-3. The newly added limitation "and a pharmaceutical additive, so that the composition is in a form suitable for administration to humans" in claim 24 still encompasses a product of nature, for example, human, when the composition is applied to humans. It is suggested that applicant use the language "isolated" or "purified" in connection with the inhibitors to indicate the hand of the inventor. See MPEP 2105.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is indefinite for the recitation "non-naturally occurring". This appears to be product-by-process limitation but it is not clear what distinguishes a "naturally occurring" IL-18 or IL-12 inhibitor from one that is not. The metes and bounds of the claim cannot be determined. For example, it is not clear whether an IL-18BP polypeptide produced by peptide synthesis but having the same sequence as the IL-18BP polypeptide isolated from a natural source would be considered to be naturally occurring. Further, as not all "naturally-occurring" forms of IL-18 or IL-12 inhibitors are known or defined, the metes and bounds of the claim cannot be unambiguously determined.

The remaining claims are included in this rejection because they are dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 34, 35, 38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Parnet et al., US 5,776,731.

Parnet discloses a human receptor protein, designated "2F1" (SEQ ID NO:2), which is now known as IL-18 receptor (IL-18R). Additionally, Parnet teaches the soluble form of the receptor, and pharmaceutical compositions thereof, which can be used for disease treatment (column 10, lines 48-49, and column 13, lines 23-25), and that components that are commonly employed in pharmaceutical formulations include those described in *Remington's Pharmaceutical Sciences*, 16th ed., 1980, Mack Publishing Company (column 13, lines 25-28), which is known to include formulations such as tablets, isotonic agent solution, etc., and they are suitable for administration to humans. As such, the reference anticipates claims 24, 34, 35 and 38. Further, Parnet teaches antibodies to the 2F1 including monoclonal and humanized antibodies (column 13, line 55-60, and column 14, lines 7-9), and pharmaceutical compositions thereof, which can be used for therapeutic purpose in vivo (column 14, lines 32-34 and 38-42), and that wherein Further, suitable components of the pharmaceutical compositions are as described above for compositions containing 2F1 proteins. Therefore, the reference also anticipates claim 40.

Claim 24 remains rejected, and the new claims 34 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Gillis (US4,411,993), for the reasons of record set forth in the last Office Action mailed on 29 June 2006, at pages 3-4, and for the reasons below.

Applicants argument filed on 22 March 2007 has been fully considered, but is not deemed persuasive for reasons below.

At page 7 of the response, the applicant argues that Gillis uses IL inhibitors to test samples extracted to a living body, but they are not intended to be administered to humans and are not formed into a suitable pharmaceutical composition. This argument is not persuasive because the reference does not explicitly mention that the hybridoma supernatants cannot be administered to humans, and media are considered pharmaceutically acceptable carriers. Applicants have not provided any evidence to the contrary. Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on (*In re Best, Bolton, and Shaw*, (CCPA) 195 USPQ 430). As such, the reference anticipates the present claims 24, 34 and 39.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 33, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parnet et al., US 5,776,731 as applied to claims 24, 34, 35, 38 and 40 above.

The teachings of Parnet are reviewed above. Although the reference does not specify a dose of the composition (as claims 32 and 36), it further teaches that components of the compositions will be nontoxic to patients at the dosages and concentrations employed (column 13, lines 36-37), indicating that a person having ordinary skill in the art would be able to determine such a dose. Further, given the fact that the recited dose of "0.1 to 1000 mg" in the present claims represents a very broad dose range (10^4 magnitude); the fact that it seems to be merely a packing dose as there is no particular disease/condition associated with the dose; and the fact that there is no particular IL-18 inhibitor recited, an artisan would, without a choice, *have to* determine a suitable dose (for packing or for therapeutic convenience) for any given IL-

18 inhibitor. Such determination is well within the purview of a person of ordinary skill in the art.

Conclusion:

No claim is allowed.

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
6/6/07

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
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